

REMARKS

The present invention relates to certain antibiotics AA-896, which are useful as antibacterials.

Claims 23, 31, 33, 40, 41, 87-93, 99, 104 and 105 are pending in the application.

By the current amendment, claims 23, 31, 33, 40, 41, 87-93, 99, 104 and 105 have been amended and new claims 106-111 added.

The Examiner has objected because of the informality that the specification on page 1 fails to update the status of the parent application Serial No. 10/132,005.

In response, applicants have amended the specification on page 1 to reflect that the parent application Serial No. 10/132,005 has issued as US Patent No. 6,689,763. Applicants believe they have overcome the informality and respectfully ask the Examiner to remove the rejection.

The Examiner has rejected claims 87-93 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As stated by the Examiner, in the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter.

Applicants respectfully traverse the rejection. Applicants believe original claims 87-93 met the requirements of 35 U.S.C. 101. However Applicants have amended the claims to more clearly point to the "hand of man." Claim 87 has been amended to add the word "cultivated" to show the "hand of man" which is supported throughout the specification. Claims 88-93 are dependent upon claim 87. In addition claims 88-93 have been further amended to add "prepared by mutagenesis of strain LL4774" as described in the specification on pages 18-19 to provide non-naturally occurring mutants.

Applicants believe they have overcome the rejection under USC 35 101 by showing that the strains produced required the "hand of man" to form non-naturally occurring mutants. Applicants respectfully ask the Examiner to reconsider the rejection and allow the claims.

The Examiner has rejected under 35 USC 112 first paragraph, claims 23, 31, 33, 40, 41, 87-93, 99, 104 and 105 as failing to comply with the enablement requirement. The terminology "mutant thereof" lacks enablement. The Examiner contends that the terminology "mutant thereof" (all occurrences) lacks enablement in that it encompasses all possible mutants of the claimed microorganism, including those which are not capable of producing antibiotics.

Applicants respectfully traverse the rejection. Applicants have amended claims 23, 31, 33, 40, 41, 87-93, 99, 104 and 105 to replace the phrase "mutant thereof" with

the phrase "or an antibiotic producing mutant thereof" in claims 23, 31, 33, 40, 41, 87, 99, and 104 so as not to encompass "all mutants" as described by the Examiner.

In further response, applicants point the Examiner to page 18, lines 4-24 and page 19, lines 2-17 of the specification where mutant strains are produced as described through the method of mutagenesis forming mutagenized cells. The mutants so produced are then isolated and purified and have been deposited. The mutagenized cells are further cultivated by procedures described throughout the specification and in particular on page 25, lines 18-32 and page 26, lines 5-15.

Support for the added phrase "prepared by mutagenesis of strain LL4774" may be found throughout the specification and in particular on page 18 wherein lines 22-24 describe mutants accumulating LL-AA896 components.

Applicants believe they have provided enablement in the form of deposited strains and adequate description throughout the specification on how to produce mutants capable of producing antibiotics. Applicants believe they have overcome the rejection and respectfully ask the Examiner to reconsider and allow the claims.

The Examiner has rejected claims 87-93 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Michel et al (US Patent No. 4,316,959) or Kamogashira et al (US Patent No. 4,332,891).

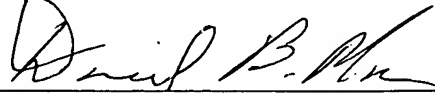
As described by the Examiner, each of Michel et al and Kamogashira et al discloses a microorganism *Streptomyces*. The claimed microorganisms are anticipated by Michel et al and Kamogashira et al. In addition, if there are any differences between the claimed microorganisms and the references microorganisms, the differences would appear to be minor in nature and the claimed microorganisms, which fall within the scope of the prior art's disclosure, would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made.

In response, applicants respectfully traverse the rejection. Applicants believe that the present invention is patentable over the cited references. As a first matter, Applicants believe that the Examiner has failed to meet his burden that the cited references anticipate or render obvious the present invention. Applicants believe that the prior art references cited by the Examiner simply do not provide a suggestion or expectation why one of ordinary skill in the art would be lead to produce the microorganisms of the claimed invention. Furthermore Applicants would point out that the microorganism *Streptomyces sp.* NRRL 12067, described in US Pat. No. 4,316,959 produces the antibiotic A-32256 which has a chemical structure very different from the chemical structures of the Antibiotics AA-896 of the instant invention. Also, the microorganism *Streptomyces sp.* OFR 1022 described in US Pat. No. 4,332,891 produces the known antibiotic Cephameycin C. Cephameycin C is a cephem-4-carboxylic acid which has a chemical structure much unlike the chemical structures of the Antibiotics AA-896 of the instant invention. Applicants believe that there is no motivation or teaching in the above described art which would lead one to believe or expect that the antibiotics AA-896 would be produced by the organisms, NRRL 12067 and OFR 1022. Applicants submit that because the products from the cultivation are very different, it would be very unlikely that the differences between the organisms in claims 87-93 of the instant invention and those described in the art are minor as alleged by the Examiner.

Applicants respectfully ask the Examiner to reconsider the rejections and remove the 35 USC 102(b) and 35 USC 103(a) rejections and allow the claims.

With the present amendment, and for the reasons presented hereinabove, this application is believed to be in condition for allowance. The prompt sending of a notice thereof is believed to be in order and is respectfully solicited.

Respectfully submitted,



Daniel B. Moran
Agent for Applicants
Reg. No. 41,204

Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940
Tel. No. (845) 602-845-2224